ST

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,422	07/03/2001	Rudolf Hauptmann	98,385-H	8840

20306 7590 03/07/2006

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
O HARA, EILEEN B	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,422	HAUPTMANN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,23,41,42,45-48 and 50-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42* is/are allowed.

6)☒ Claim(s) *1,23,41,45,48 and 50-53* is/are rejected.

7)☒ Claim(s) *46 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 23, 41, 42, 45-48 and 50-53 are currently pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 23, 41, 42, 45-48 and 50-53 remain rejected under 35 U.S.C. 102(e) as being anticipate by Wallach et al., U.S. Patent No. 5,981,701, effective priority date Sept. 12, 1988, and Wallach et al., U.S. Patent No. 5,695,953, priority date Sept. 12, 1988, as noted in the previous Office Action mailed August 25, 2005, at pages 3-5, and below.

Applicants traverse the rejection and assert that to support a rejection under 35 U.S.C. § 102, and state:

> "the four comers of a single, prior art document (must) describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). The exclusion of even a single claimed element from a reference, no matter how insubstantial or obvious, is enough to negate anticipation. Connell v. Sears, Roebuck& Co., 220 U.S.P.Q. (BNA) 193, 198 (Fed. Cir. 1983). The identical invention must also be shown in the single prior art reference in as complete detail as contained in the application against which the reference is cited. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 198%. Moreover, the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. M.P.E.P § 2121.01; Elan

Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. zoè3jiAmgen, Inc. v. Hoechst Marion Roussel , Inc., 126 F. Supp. 2d 69, 88 (17. Mass 2001) (citing Akzo N.V. v. United States Int'l Trade Comm 'n, 808 F.2d 1471, 1479 (Fed. Cir. 1986)). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. M.P.E.P § 2121.01. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his (or her) own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531 (Fed. Cir. 1985)."

Applicants assert that the Wallach patents provide only a partial, incomplete amino acid sequence of a TNF inhibitory protein - and no nucleotide sequence whatsoever, and contend that because the Wallach patents do not disclose the complete nucleotide and amino acid sequence of TNF binding protein - and in fact, disclose only fourteen of the first sixteen amino acid residues of a TNF inhibitory protein - the reference cannot anticipate a recombinant polypeptide having the ability to bind TNF, wherein said polypeptide is encoded by a nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO: 3, or comprises the amino acid sequence as set forth in SEQ ID NO: 4. Applicants assert that there is no evidence in the Wallach patents that the small fragment for which the sequence has been disclosed has the ability to bind TNF, a recited limitation of the instantly claimed methods.

Applicants' arguments have been fully considered but are not deemed persuasive. Wallach does not teach or claim that the 14 amino acid fragment binds TNF – Wallach teaches that the TNF binding protein has a molecular weight of about 26-28 Kda when analyzed by SDS PAGE under reducing conditions. The 14 amino acid sequence disclosed just identifies the N-terminus of the protein. Additionally, the Wallach patents demonstrate that this TNF binding protein has activity. Two assay procedures were used for monitoring the activity of the TNF Inhibitory Protein in the different fractions during the purification process, inhibition of binding

of TNF-.alpha. to its receptor, and quantitation of TNF binding to cells (column 6, line 52 to column 7, line 57).

Applicants also note that the Wallach patents disclose a TNF binding protein purified from human urine by use of dialysis, ion exchange chromatography, and reverse phase high pressure liquid chromatography. Applicants contend that because the TNF binding protein disclosed in the Wallach patents is purified from urine, these references cannot anticipate a recombinant polypeptide having the ability to bind TNF. In particular, Applicants contend that, in light of the specification's teachings and knowledge in the art, one of ordinary skill in the art would readily understand that a substantially homogeneous TNF binding protein purified from urine would not be free of human urinary proteins, and that the recombinantly produced TNF binding protein of Applicants' invention must be inherently free of human urinary proteins, and that only Applicants' invention provided the nucleic acid sequence of TNF binding protein, which was absolutely necessary, in order to recombinantly produce TNF binding protein.

Applicants' arguments have been fully considered but are not deemed persuasive. Wallach demonstrated that the highly purified TNF binding protein moves as a single peak on reversed-phase high performance liquid chromatography (HPLC), and therefore is free of urinary proteins.

Applicants also contend that the assertion that pharmaceutical compositions comprising a purified TNF binding protein anticipate methods that use a recombinant TNF binding protein is entirely analogous to the assertion, made in Amgen, Inc. v. Hoechst Marion Roussel, Inc., that erythropoietin purified from patients with anemia anticipates recombinant erythropoietin. 126 F.

Supp. 2d 69, 88 (17. Mass 2001) (holding that a reference disclosing erythropoietin purified from patients with anemia does not anticipate claims to recombinant erythropoietin).

Applicants' arguments have been fully considered but are not deemed persuasive. The reason that the court determined that the reference disclosing erythropoietin purified from patients with anemia did not anticipate claims to recombinant erythropoietin was because Amgen demonstrated in its patents (for example Patent No. 5,547,933, column 28, line 33 to column 29, line 7), that the EPO produced by CHO or COS cells had a higher molecular weight and a different glycosylation pattern from EPO purified from human urine (page 1464 of Amgen, Inc. v. Hoechst Marion Roussel, Inc.). Applicants have not provided any evidence that their recombinantly produced TNF binding protein differs in molecular weight or glycosylation pattern.

Applicants also argue that because the Wallach patents fail to disclose the nucleic acid sequence of TNF binding protein, these references fail to put a recombinant TNF binding protein into the public's possession, and thus, do not contain an enabling disclosure with respect to a recombinant TNF binding protein, and the Wallach patents do nothing more than merely recite that a TNF binding protein isolated from human urine can be recombinantly produced. Applicants, therefore, contend that the Wallach patents cannot anticipate the claimed methods of the present application.

Applicants' arguments have been fully considered but are not deemed persuasive. Because the claims are drawn to the recited TNF binding protein, and there is no evidence of record that the protein purified from urine differs from the recombinantly produced protein, the

Wallach patents anticipate the claimed invention. For these reasons, the rejection is maintained.

For these reasons, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

3.1 Claim 42 is allowed.

3.2 Claims 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

3.3 Claims 1, 23, 41, 45, 48 and 50-53 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PRIMARY EXAMINER